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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/760,307	01/11/2001	Sam J. Milstein	1946/1A483-US8	8759
7590	12/30/2003		EXAMINER	
DARBY & DARBY P.C. 805 Third Avenue New York, NY 10022			CHANNAVAJJALA, LAKSHMI SARADA	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 12/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/760,307	MILSTEIN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Lakshmi S Channavajjala	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 22 September 2003.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 13-37,50-74 and 87-189 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 13-37,50-74 and 87-189 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. §§ 119 and 120

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.
- 13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
  - a) The translation of the foreign language provisional application has been received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

#### Attachment(s)

- |   |   |
|---|---|
| <input type="checkbox"/> Notice of References Cited (PTO-892)                               | <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)           | <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)  |
| <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | <input type="checkbox"/> Other: _____ .                                   |

## DETAILED ACTION

Receipt of request for extension of time and amendment B dated 9-22-03 is acknowledged.

Claims 13-37, 50-74 and 87-189 are pending.

### *Response to Arguments*

Applicant's arguments filed 9-22-03 have been fully considered but they are not persuasive.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 13-16, 18, 23-25, 27, 32, 50-53, 55, 60-62, 64, 69, 87-90, 92, 97-99, 101, 106 and 112-127 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,873,087 to Morishita et al (Morishita) or US 4,442,090 to Kakeya et al (Kakeya).

**Applicants argue that the preamble in each of the claims is limiting since it is necessary to give life, meaning and vitality to claims. Applicants argue that neither Morishita or nor Kakeya disclose or suggest the claimed (subcutaneous, sublingual or intranasal delivery routes) and instead teach rectal administration. However, applicants' arguments are not persuasive because applicants did not argue the fact that the cited references disclose or suggest the components of the claimed composition. While the references teach rectal compositions, instant claims do not specifically distinguish the claimed composition from that of the prior art compositions so as render the compositions**

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**of prior art unsuitable for the claimed routes of delivery. Absent any feature that limits the compositions specific to the claimed delivery routes, the preamble carries no patentable weight and the compositions of Morishita and Kakeya are suitable for administration via the claimed routes. Therefore, the rejection has been maintained.**

**Examiner noted that new claims 128-189 are been added that depend from previously rejected claims. The present rejection under 35 U.S.C. 103(a) also applies to the new claims for the reasons mentioned in the outstanding non-final rejection.**

***Double Patenting***

Claims 13-37, 50-74 and 87-127 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 6,071,538.

Claims 13-37, 50-74 and 87-127 are rejected under 35 U.S.C. 103(a) as being unpatentable over 6,017,538 (hereafter '538).

Claims 13-37, 50-74 and 87-127 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-39 of U.S. Patent No. 6,221,367. Although the conflicting claims are not identical, they are not patentably distinct from each other because the perturbant of the patented claims is a species the generic perturbants claimed in the instant invention.

**Examiner maintained the above double patenting rejection because applicants expressed their willingness to file a terminal disclaimer upon finding allowable subject matter.**

**New rejections with respect to the amended claim 28:**

Claim 28 is objected as being improper because it depends from a canceled claim 46.

Claim 28 recites the limitation "a method" in line 1. There is insufficient antecedent basis for this limitation in the claim.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S Channavajjala whose telephone number is 703-308-2438. The examiner can normally be reached on 7.30 AM -4.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-7924 for regular communications and 703-308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Lakshmi S Channavajjala  
Examiner  
Art Unit 1615  
December 28, 2003

THURMAN K PAGE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600